



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service *g 5032H*

Food and Drug Administration
5100 Paint Branch Pkwy, HFS-607
College Park, Maryland 20740

OCT 22 2004

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Reliant World Products, Inc.
P.O. Box 100627
San Antonio, Texas 78201

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.miracletab.com> and has concluded that claims on this web site cause your product "Miracletab" to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. [21 U.S.C. § 343(r)(6)(A).] One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading. [21 U.S.C. § 343(r)(6)(B).]

The labeling of Miracletab bears structure/function claims, including the following:

- "With Miracle tab diet pill, you Can Lose Up To 90 Lbs and be 8 Sizes smaller in 90 days![Y]ou don't need to exercise or diet."
- "[H]elp bind and dispose your fat and suppress your appetite...."
- "The following are the key active ingredients: 1) Chitosan is an all natural ingredient that is added to attract and bind your fats and then dispose of them. 2) The unique banaba extract ... helps convert your sugar and carbs into energy."

We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of sections 403(a)(1) and 403(r)(6)(B) of the Act. [21 U.S.C. § 343(a)(1), (r)(6)(B).] It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded. [21 U.S.C. § 331(a).] It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is

Page 2- Reliant World Products, Inc.

done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. [21 U.S.C. § 331(k).]

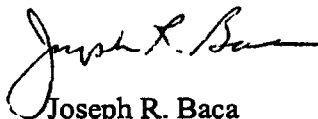
This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action, including seizure or injunction, without further notice.

If you have scientific evidence which you believe substantiates that your claims for Miracletab are truthful and not misleading, please provide it to us within fifteen (15) working days of receipt of this letter. Alternatively, please advise this office, in writing and within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to ensure that similar violations do not occur in the future. If corrective action cannot be completed with fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joseph R. Baca". The signature is fluid and cursive, with a long horizontal stroke at the end.

Joseph R. Baca

Director

Office of Compliance

Center for Food Safety and Applied Nutrition